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| 10/635,439 | 08/07/2003 | Ross Clark | 012047.00036 | 8576 |

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EXAMINER

SOROUGH, ALI

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/635,439 | Applicant(s) CLARK, ROSS | |
| | Examiner Ali Soroush | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) 14-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to a film and/or film composition comprising pectin and an active agent, classified in class 424, subclass 49.
- II. Claims 14-15, drawn to a method of delivering breath freshening agent comprising a pectin and active gent to the oral cavity, classified in class 424, subclass 49.
- III. Claims 16-27, drawn to a process of making pectin film, classified in class 536, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the film and/or film composition of Group I can be used to achieve actions other than freshening breath, e.g. introducing a pharmaceutical to the oral cavity. Also, the method of delivering breath freshening agent to the oral cavity of Group II can be performed by another product other than a film, e.g. in the form of a capsule containing the breath freshening agent. In searching Group II the examiner will be focusing on the patentability of the

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method of delivering breath freshening agent to the oral cavity and not the composition and/or a film comprising a pectin film and an active agent of Group I.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, a film and/or film composition comprising pectin and an active agent can be made by a variety of different methods. One such example would be to use pectin already at the desired intrinsic viscosity for producing the film or film composition. Also, pectin made by the method of Group III can be used in a variety of other products, e.g. in a composition to make a gelatinous substance for consumption. In searching Group I the examiner will be focusing on the patentability of the film and/or film composition comprising pectin and an active agent. Conversely, in searching Group III the examiner would be focusing on the patentability of active method steps of making pectin with a specific intrinsic viscosity.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of delivering breath freshening agent to the oral cavity of Group II can be performed by a variety of methods utilizing pectin with a wide range of intrinsic viscosities. Also, pectin made by the method of Group III can be used in a variety of other products, e.g. in a composition to make a gelatinous substance for consumption. In searching Group II the examiner will be focusing on the patentability of the method of

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delivering breath freshening agent to the oral cavity. Conversely, in searching Group III the examiner would be focusing on the patentability of a method of making pectin with a specific intrinsic viscosity.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Election of Species

When applicant elects any of the Groups I, II, or III an election of species is required. This application contains claims directed to the following patentably distinct species: a plurality of active agents.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims of Group I II, and III read a plurality of active agents, the search for all of which presents an undue burden on the Office.

Election

During a telephone conversation with Jane Shershenovish on September 7, 2006 at 10:30 am a provisional election was made without traverse to prosecute the invention of Group I, claims 1-13. Also, a provisional species election was made without traverse

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as to the active agent being a flavoring agent. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2,5-9,12,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (US 2001/0022964).

Applicant Claims

Applicant claims a film and/or a film composition comprising pectin with an intrinsic viscosity of about 2.5 dl/g or less and at least one bioactive agent such as a flavoring agent for consumption and delivery of a bioactive agent.

Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)

Leung et al. teaches fast dissolving orally consumable films. The film comprises at least one water-soluble polymer and the essential oils as antimicrobial/flavoring agents, and can further comprise water, additional antimicrobial agents, film-forming agents, flavoring agents including those known to the skilled artisan such as natural and artificial flavorings, etc. (title; column 4, paragraph 34; and column 6, paragraph 52). The film-forming agent used in the films can be selected from the water-soluble polymer group consisting of pullulan, dextrin, pectin, etc. (column 4, paragraph 33). The consumable film comprises: about 40 to about 80 wt% pullulan (water soluble polymer), about 0.01 to about 4 wt % thymol, about 0.01 to about 4 wt % methyl salicylate, about 0.01 to about 4 wt % eucalyptol; about 0.01 to about 15 wt % methanol (claim 9).

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims
(MPEP §2141.012)***

Leung et al. lacks the teaching of the intrinsic viscosity of pectin. Also, Leung lacks the teaching of the concentration pectin in the film.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to use pectin in place of pullulan in the film composition described in Leung et al. (claim 9). Leung et al. teaches a number of water-soluble polymers including pullulan and pectin. Leung et al. does not distinguish between the polymers, which suggests that in Leung et al.'s context the polymers in the list presented are equivalent in function at least in Leung's invention. Therefore, Leung et al. makes obvious the use of about 40 to about 80 wt% of pectin in the film composition which falls within the instant amount of pectin ranging from about 20 to about 80% by weight pectin in the film. With regard to the intrinsic viscosity of pectin of about 2.5 dl/g and about 1.8 dl/g or less, Leung et al. is silent to the intrinsic viscosity of pectin which suggests that a broad range of pectin viscosities would work possibly even in the narrower viscosities recited in the claims. In the absence of a showing of the criticality of the narrower intrinsic viscosity disclosed in the instant invention, Leung makes obvious the instant intrinsic viscosity. In addition, the intrinsic viscosity of pectin being used in Leung et al. cover the instant amount (2.5 dl/g or less) since through routine experimentation of Leung et al.'s invention can lead an artisan arriving at the instant intrinsic viscosity being used. One would have been motivated to do this in order to develop a composition that would have been effective as an orally soluble film while also maintaining its film like structure prior to use.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (US 2001/0022964) in view of Hoagland (US 5,919,574).

Applicant Claims

Applicant claims a film and/or a film composition comprising pectin with an intrinsic viscosity of about 2.5 dl/g or less and at least one bioactive agent such as a flavoring agent for consumption and delivery of a bioactive agent. Wherein, the pectin is either high or low methyl ester pectin.

Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)

Leung et al. teaches fast dissolving orally consumable films. The film comprises at least one water-soluble polymer and the essential oils as antimicrobial/flavoring agents, and can further comprise water, additional antimicrobial agents, film-forming agents, flavoring agents include those known to the skilled artisan such as natural and artificial flavorings, etc. (title; column 4, paragraph 34; and column 6, paragraph 52). Leung et al. teaches a number of water-soluble polymers including pullulan and pectin. Leung et al. does not distinguish between the polymers, which suggests that in Leung et al.'s context the polymers in the list presented are equivalent in function at least in Leung's invention. Therefore, Leung et al. makes obvious the use of about 40 to about 80 wt% of pectin in the film composition which falls within the instant amount of pectin ranging from about 20 to about 80% by weight pectin in the film. With regard to the intrinsic viscosity of pectin of about 2.5 dl/g and about 1.8 dl/g or less, Leung et al. is silent to the intrinsic viscosity of pectin which suggests that a broad range of pectin viscosities would work possibly even in the

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narrower viscosities recited in the claims. In the absence of a showing of the criticality of the narrower intrinsic viscosity disclosed in the instant invention, Leung makes obvious the instant intrinsic viscosity. In addition, the intrinsic viscosity of pectin being used in Leung et al. cover the instant amount (2.5 dl/g or less) since through routine experimentation of Leung et al.'s invention can lead an artisan arriving at the instant intrinsic viscosity being used. One would have been motivated to do this in order to develop a composition that would have been effective as an orally soluble film while also maintaining its film like structure prior to use.

Hoagland teaches laminated film having one layer consisting of pectin and at least one chitosan film layer, and said pectin has a high molecular weight, large radius of gyration, a degree of methyl esterification is at least about 50%, and intrinsic viscosity is at least about 2.1 dl/g (claim 1 and 2). The laminates of this invention are useful for a number of applications including medicinal applications such as patches for the delivery of pharmaceuticals to skin.

Ascertainment of the Difference Between Scope of the Prior Art and the Claims

(MPEP §2141.012)

Leung et al. lacks the teaching of the intrinsic viscosity of pectin. Also, Leung lacks the teaching of the type of pectin (high or low methyl ester pectin) that is used in the film and/or film composition of the instant invention. These deficiencies are cured by the teachings in Hoagland.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Leung et al. and Hoagland, because Leung teaches an orally consumable film made from pectin that is intended to deliver a bioactive agent and Hoagland teaches a film made of pectin and chitosan that is used to deliver a pharmaceutical (bioactive). It is recognized in the art that the components of film taught by Hoagland including chitosan can be orally consumed (Taniguchi et al.; JP 61051851). The teaching of intrinsic viscosity of at least about 2.1 dl/g of Hoagland falls very well within the range of about 2.5 dl/g or less and about 1.8 dl/g or less of the instant claim since through routine experimentation of Hoagland's invention can lead an artisan arriving at the instant intrinsic viscosity being used. One would have been motivated to attain this viscosity because it would make a fast dissolving orally soluble film that would not be brittle and crack. I would have been obvious to include the methyl ester pectin taught by Hoagland in the invention of Leung et al. One would have been motivated to this since both references individually teach that pectin films are consumable friendly and effective in drug delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention that the methyl ester pectin of Hoagland very well covers the high and low methyl ester pectin of the instant invention. The instant specification defines high methyl ester pectin as having higher than 50% degree of esterification and low methyl ester pectin as having less than 50% degree of esterification. With regard to the type of pectin used in the film composition Hoagland teaches at least about 50% methyl esterification. The phrase "at least about 50%" would

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suggest at least 50% and about 50%. About 50% would lead an artisan to films where the amount of methyl ester pectin is from 40 to about 50%. Therefore, in the absence of unexpected results Hoagland's teaching of at least 50% and suggests lower percents, e.g. 40- 49.9%. Based on the combination of these references the invention is made obvious.

Other Matters

At this time the cited patent JP 61051851 is being translated into English. Upon completion of translation it will be faxed to the applicants for their consideration.

Conclusion

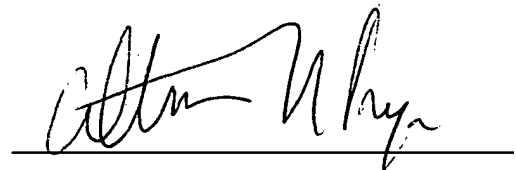
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
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A handwritten signature in black ink, appearing to read 'Alton Pryor', is written over a horizontal line.

Alton Pryor
Primary Patent Examiner
Technology Center 1600